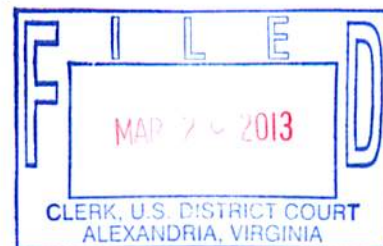


IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION



UNIVERSITY OF FLORIDA )  
Research Foundation, Inc. )  
223 Grinter Hall )  
Gainesville, Fla 32611 )

Plaintiff, )  
v. )

Civil Action No. 1:13CV407 CMH/TCB

HON. TERESA STANEK REA )  
Acting Under Secretary of Commerce for )  
Intellectual Property and )  
Acting Director of the )  
United States Patent and Trademark Office )  
P.O. Box 1450 )  
Alexandria, Virginia 22313-1450 )  
401 Dulany Street )  
Alexandria, Virginia 22314 )

Office of General Counsel )  
United States Patent and Trademark Office )  
P.O. Box 1450 )  
Alexandria, VA 22313-1450 )  
Madison Building East, Rm 10B20 )  
600 Dulany Street )  
Alexandria, VA 22314 )

Defendant. )

**COMPLAINT**

Plaintiff the University of Florida Research Foundation, Inc. ("Florida" or "Plaintiff") for its complaint against the Honorable Teresa Stanek Rea ("Rea"), states as follows:

**NATURE OF THE ACTION**

1. This is an action by Plaintiff, the assignee, sole owner of United States Patent No. 8,278,458 (the "'458 Patent") seeking review of the denial of the correct patent term adjustment

for the '458 Patent by the Defendant Acting Director of the United States Patent and Trademark Office ("USPTO"). Plaintiff seeks a judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '458 Patent be corrected to be 1097 days rather than 843 days.

2. This action arises under 35 U.S.C. § 154, the Fifth Amendment of the Constitution of the United States, and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

### **THE PARTIES**

3. The University of Florida Research Foundation, Inc. is a corporation organized under the laws of Florida and having a principal place of business at 223 Grinter Hall, Gainesville, Florida 32611.

4. Defendant Teresa Stanek Rea is the Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the USPTO, acting in her official capacity. Rea, as the head of the USPTO, is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by statute as the official responsible for determining the period of patent term adjustments under 35 U.S.C. § 154.

### **JURISDICTION AND VENUE**

5. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), 1361, 2201 and 2202, 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706.

6. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

### **FACTS**

7. Raymond J. Bergeron, Jr. ("Bergeron") is the sole inventor listed on U.S. patent application 11/973,001 (the "'001 application"), which has now issued as the '458 Patent. The '458 Patent is attached hereto as Exhibit A.

8. The University of Florida Research Foundation, Inc. is the assignee of the '458 Patent.

9. The '001 application is a continuation application of International Application No. PCT/US2006/010945, filed on March 22, 2006 which claims priority to United States Provisional Application, U.S. serial number 60/668,045, filed on April 4, 2005.

10. Inventor Bergeron assigned his rights to the University of Florida Research Foundation, Inc. on April 9, 2008, as evidenced by an assignment recorded at the USPTO on April 22, 2008, at Reel/Frame 020836/0447, and as indicated on the face of the '458 Patent. As such, the University of Florida Research Foundation, Inc. is the real party of interest.

11. The '458 Patent is licensed to The United States of America as Represented by the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS). The '458 Patent is licensed to The United States of America under the Bayh-Dole Act (35 U.S.C. §§ 200-212).

12. A confirmatory license from the University of Florida to the National Institutes of Health (NIH), the United States Department of Health and Human Services (DHHS) and the United States Government was recorded at the USPTO on April 14, 2009, at Reel/Frame 022540/0688.

13. The United States of America as represented by the National Institutes of Health (NIH) and The United States of America as represented by the Department of Health and Human Service are listed as Assignees on the front of the '458 Patent.

14. Section 154 of 35 U.S.C. requires that the Director of the USPTO grant a patent term adjustment in accordance with the provisions of section 154(b). Specifically, 35 U.S.C. § 154(b)(3)(D) states that "[t]he Director shall proceed to grant the patent after completion of the



Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination."

15. In calculating the patent term adjustment, the Director must account *inter alia* for USPTO delays under 35 U.S.C. § 154(b)(1) and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

16. Under 35 U.S.C. § 154(b)(1)(A), an applicant is entitled to a patent term adjustment for the USPTO's failure to carry out certain acts during processing and examination within defined deadlines ("A Delay").

17. Under 35 U.S.C. § 154(b)(1)(B), an applicant is entitled to additional patent term adjustment attributable to the USPTO's "failure ... to issue a patent within 3 years after the actual filing date of the application in the United States," but not including "any time consumed by continued examination of the application requested by the applicant under section 132(b)" ("B Delay").

18. Defendant has calculated the patent term adjustment in a manner that deprives patentees of B Delay due to an incorrect interpretation of the effect of the continued examination procedure under 35 U.S.C. § 132(b) within the context of 35 U.S.C. § 154(b)(1)(B).

19. Defendant has inappropriately promulgated and relied upon 37 C.F.R. § 1.703(b)(1) to support its incorrect interpretation of 35 U.S.C. § 154(b)(1)(B) that B Delay permanently ceases to accrue upon the filing of a Request for Continued Examination ("RCE") by an applicant.

20. Instead, 35 U.S.C. § 154(b)(1)(B)(i) merely requires the exclusion of "any time consumed by continued examination of the application requested by the applicant under 35

U.S.C. § 132(b)” when calculating whether the USPTO has satisfied the three-year pendency guarantee.

21. As properly construed, if the USPTO fails to meet this three-year pendency guarantee, the applicant is entitled to the full remedy afforded by 35 U.S.C. § 154(b)(1)(B): “the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued,” subject only to the specific limitations set forth in 35 U.S.C. § 154(b)(2).

22. None of the limitations specified in 35 U.S.C. § 154(b)(2) reduce or otherwise affect the patent term adjustment remedy in 35 U.S.C. § 154(b)(1)(B) on the basis of time consumed by examination after filing of an RCE.

23. The USPTO promulgated regulations pursuant to 35 U.S.C. § 154(b)(2)(C) specifying applicant actions that will result in a reduction of the additional patent term adjustment specified under § 154(b)(1)(B). These regulations, set forth at 37 C.F.R. § 1.704, likewise do not include any reduction or limitation based upon time consumed by examination after the filing of an RCE.

24. Accordingly, the plain language of 35 U.S.C. § 154(b)(1)(B) dictates that if an RCE is not filed within three years after the actual date of filing of a patent application, the filing of an RCE has no effect upon the accrual of B Delay for that patent. Under such circumstances, the applicant is entitled to B Delay from the day after the three-year pendency period through the date of issuance of the patent, the explicit remedy set forth in 35 U.S.C. § 154(b)(1)(B), subject only to the specific limitations set forth at 35 U.S.C. § 154(b)(2).

25. To the extent that 37 C.F.R. § 1.703(b)(1) conflicts with the plain and unambiguous language of 35 U.S.C. § 154(b)(1)(B), this subsection of the regulation is invalid.



26. In the alternative, even if the remedy afforded under 35 U.S.C. § 154(b)(1)(B) is not determined to be limited by “any time consumed by continued examination of the application requested by the applicant under section 132(b),” the USPTO still has improperly calculated the patent term adjustment in a manner that deprives patentees of B Delay due to its incorrect interpretation of the effect of the filing an RCE.

27. On November 1, 2012, in the United States District Court for the Eastern District of Virginia (*Exelixis, Inc. v. Kappos*, No. 1:12cv96, 2012 U.S. Dist. LEXIS 157762 (E.D. Va. Nov. 1, 2012))(“*Exelixis I*”), Judge Ellis declared and ordered that an RCE filed in a patent application more than three years after the filing date for that patent application has no effect on patent term adjustment, and that “RCE’s operate only to toll the three year guarantee deadline, if, and only if, they are filed within three years of the application filing date. Thus, the PTO erred in construing subparagraph (B) to the contrary.” *Id.* at \*6.

28. The USPTO filed a notice of appeal in *Exelixis I* on December 31, 2012.

29. On November 15, 2012, the United States District Court for the District of Columbia in *Novartis AG v. Kappos*, No. 10-cv-1138 (D.D.C. Nov. 15, 2012) adopted the rationale of Judge Ellis in *Exelixis I* to determine that the USPTO’s determination of patent term adjustment is contrary to the plain and unambiguous language of § 154(b)(1)(B) and that it contravenes the structure and purpose of the statute.

30. On January 28, 2013, in a second *Exelixis* case in the United States District Court for the Eastern District of Virginia (*Exelixis, Inc. v. Kappos*, No. 1:12cv574 (E.D. Va. 2013))(“*Exelixis II*”), Judge Brinkema rejected Judge Ellis’s holding in *Exelixis I* and affirmed the USPTO’s interpretation of 35 U.S.C. § 154(b)(1)(B) that an RCE effects upon the accrual of B Delay for a patent regardless of when the RCE was filed.

31. Exelixis, Inc. filed a notice of appeal in *Exelixis II* on February 6, 2013.

**CLAIM FOR RELIEF**

**COUNT ONE**

**(Patent Term Adjustment Under 35 U.S.C. § 154)**

32. The allegations of paragraphs 1-31 are incorporated in this claim for relief as if fully set forth.

33. The patent term adjustment for the '458 Patent, as determined by the Defendant under 35 U.S.C. § 154(b), and listed on the face of the '458 Patent, is 843 days. (See Ex. A at p.1). The determination of the 843 day patent term adjustment is in error in that, pursuant to 35 U.S.C. § 154(b)(1)(B), the USPTO failed to extend the term of the patent by one day for each day after the end of a three-year period commencing with the actual filing date of the '001 application until the issue date of the '458 Patent. The correct patent term adjustment for the '458 Patent is 1097 days.

34. The '001 application was filed on October 4, 2007 and issued as the '458 Patent on October 2, 2012. (See Ex. A at p.1)

35. An RCE was filed in the '001 application on June 27, 2011. The RCE was filed more than 3 years from the filing date of the '001 application. The RCE including a certificate of electronic filing is attached hereto as Exhibit B.

36. Under 35 U.S.C. § 154(b)(1)(A), a period of 764 days is attributable to USPTO examination delay (A Delay). The total period of A Delay is the aggregate of two separate periods.

37. Under 35 U.S.C. § 154(b)(1)(A)(i), a period of 554 days from December 4, 2008 to June 11, 2010 is attributable to USPTO examination delay due to failure by the USPTO to



mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 not later than 14 months after the actual filing date of the application (A Delay).

38. Under 35 U.S.C. § 154(b)(1)(A)(ii), a period of 210 days from October 27, 2011 to May 24, 2012 is attributable to USPTO examination delay due to failure by the USPTO to reply under section 35 U.S.C. § 132 within 4 months after the date on which a reply was filed by Applicant (A Delay).

39. Thus, the total period of A Delay is 764 days (554 days + 210 days).

40. Under 35 U.S.C. § 154(b)(1)(B), the Plaintiff is entitled to an additional adjustment of the term of the '458 Patent of a period of 729 days from October 4, 2010 to October 2, 2012, which is the number of days the issue date of the '458 Patent exceeds a three-year period running from the actual filing date of the '001 application (B Delay).

41. The USPTO's determination of the B Delay only included the number of days exceeding a three-year period running from the actual filing date of the '001 application to the day before the RCE was filed (i.e., 265 days from October 4, 2010 to June 26, 2011).

42. Thus, the total period of A Delay + B Delay is 1493 days (764 days + 729 days).

43. Under 35 U.S.C. § 154(b)(2)(A), the total period of USPTO delay is reduced by the overlapping days between A Delay and B Delay. The total period of overlapping days between A Delay and B Delay is 210 days.

44. The total period of overlapping days between A Delay and B Delay is the period of 210 days of October 27, 2011 to May 24, 2012.

45. Thus, the total period of USPTO delay is 1283 days, which is the sum of the period of A Delay (764 days) and the period of the B Delay (729 days) minus the period of overlapping days between A Delay and B Delay (210 days).



46. Under 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of applicant delay, which is 186 days as determined by the USPTO.

47. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b)(1) and (2) is 1097 days which is the difference between the total period of USPTO delay (1283 days) and the period of applicant delay (186 days).

48. The '458 Patent is not subject to a terminal disclaimer.

49. The USPTO's erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) resulted in an incorrect calculation of the B Delay for the '458 Patent and deprived patentee of the appropriate PTA for this patent.

50. Plaintiff is entitled to additional patent term for the '458 Patent such that the 843 days of patent term adjustment granted by the USPTO should be changed to 1097 days.

## COUNT TWO

### **(Violation of the Fifth Amendment of the Constitution of the United States)**

51. The allegations of paragraphs 1-50 are incorporated in this claim for relief as if fully set forth herein.

52. The Fifth Amendment of the Constitution of the United States provides in relevant part, “[N]or shall private property be taken for public use, without just compensation.”

53. Plaintiff enjoys a substantial and cognizable private property right in the full and complete term of the ’458 Patent.

54. Plaintiff has not failed to pay any necessary maintenance fees to the USPTO required to maintain its rights in the ’458 Patent.

55. Defendant’s promulgation of 37 C.F.R. § 1.703(b)(1), the regulatory subsection interpreting 35 U.S.C. § 154(b)(1)(B)(i), and reliance upon this regulatory subsection in improperly calculating the B Delay for the ’458 Patent permanently deprived Plaintiff of the appropriate PTA for this patent to which it was entitled under 35 U.S.C. § 154(b).

56. Defendant’s purposeful and deliberate diminution of the patent term of the ’458 Patent constitutes a taking of Plaintiff’s property without just compensation, in violation of the Fifth Amendment of the Constitution of the United States.

57. Plaintiff is entitled to additional patent term for the ’458 Patent such that the 843 days of patent term adjustment granted by the USPTO should be changed to 1097 days.

### COUNT THREE

**(Declaratory Judgment Under The Administrative Procedures Act, 5 U.S.C. § 702 et seq.)**

58. The allegations of paragraphs 1-57 are incorporated in this claim for relief as if fully set forth herein.

59. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1), the regulatory subsection interpreting 35 U.S.C. § 154(b)(1)(B)(i), and its improper calculation of the B Delay when determining the patent term adjustment for the '458 Patent were contrary to law.

60. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of patent term adjustment for the '458 Patent are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A); contrary to Plaintiff's constitutional rights within the meaning of 5 U.S.C. § 706(2)(B); and in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C).

61. Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of PTA for the '458 Patent were final agency actions that are reviewable by a district court in accordance with 5 U.S.C. § 704.

62. Plaintiff has adequately exhausted all of its available administrative remedies under 35 U.S.C. § 154 or, in the alternative, pursuit of any further administrative remedies is futile.

63. Plaintiff has been afforded no adequate remedy at law for the Defendant's promulgation of 37 C.F.R. § 1.703(b)(1) and determination of patent term adjustment for the '458 Patent.

64. Plaintiff will suffer irreparable injury if 37 C.F.R. § 1.703(b)(1) is not invalidated and the Defendant is not directed to recalculate patent term adjustment for the '458 Patent.

65. There is an actual controversy between the parties within this Court's jurisdiction.



66. An order invalidating 37 C.F.R. § 1.703(b)(1) and directing the Defendant to recalculate patent term adjustment for the '458 Patent would not substantially injure any other interested parties, and the public interest will be furthered by invalidation of a regulatory subsection and recalculation of patent term adjustment that is contrary to law.

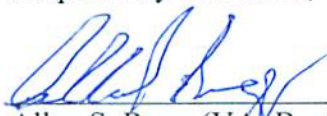
67. Plaintiff is entitled to additional patent term for the '458 Patent such that the 843 days of patent term adjustment granted by the USPTO should be changed to 1097 days.

WHEREFORE, Plaintiff respectfully prays that this Court:

1. Issue an Order changing the period of patent term adjustment for the '458 Patent term from 843 days to 1097 days and requiring the Defendant to alter the terms of the '458 Patent to reflect the 1097 day patent term adjustment.
2. Declare pursuant to 28 U.S.C. § 2201 that 37 C.F.R. § 1.703(b)(1) is invalid, unconstitutional and contrary to law; and
3. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Dated: March 28, 2013

Respectfully submitted,



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